EC CERTIFICATE

Number: 2018308CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

URSAPHARM Arzneimittel GmbH

Industriestrasse 35
66129 Saarbrücken
Germany

For the product category(ies)

Sterile Eye Care Products

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2018308CN, initially dated 19 August 2002
Addendum, initially dated 19 August 2002

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until:	1 September 2022
Issued for the first time:	19 August 2002
Revised:	12 April 2016
Reissued:	29 September 2017

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2018308CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Sterile Eye Care Products

Issued to:

URSAPHARM Arzneimittel GmbH
Industriestrasse 35
66129 Saarbrücken
Germany

This certificate covers the following product(s):

VitA-POS: eye ointment (Class IIb)

HYLO NIGHT: eye ointment (Class IIb)

HYLO-PARIN: Eye care solutions to be used for moisturization and care of cornea and conjunctiva in irritated eyes (Class III)

PARIN-POS: eye care ointment to be used for moisurization and care of cornea and conjunctiva in irritated eyes (Class III)

HYLO-CORNEAL: Eye care solutions to be used for moisturization and care of cornea and conjunctiva in irritated eyes (Class III)

Initial date: 19 August 2002
Revision date: 15 January 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

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Certification Manager

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